**THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION** | **MDL NO. 2445** |
| **THIS DOCUMENT RELATES TO:** | **Master File No. 2:13-MD-2445-MSG** |
| ***All Actions*** | |

# REPLY IN SUPPORT OF DEFENDANTS' MOTION TO RECONSIDER

Thomas Demitrack
Brett Bell
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114-1190
Telephone: (216) 586-3939
Facsimile: (216) 579-0212
E-mail: tdemitrack@jonesday.com
E-mail: bbell@jonesday.com

Kevin D. McDonald
Mark R. Lentz
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700
E-mail: kdmcdonald@jonesday.com
E-mail: mrlentz@jonesday.com

Kimberly A. Brown
JONES DAY
500 Grant Street, Suite 4500
Pittsburgh, PA 15219
Telephone: (412) 391-3939
Facsimile: (412) 394-7959
E-mail: kabrown@jonesday.com

*Counsel for Defendants Reckitt Benckiser Inc.; Reckitt Benckiser LLC; Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) Ltd.; and Reckitt Benckiser Group plc.*

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Despite the care that the Court put into its December 3rd opinion, three of Reckitt Benckiser Pharmaceuticals, Inc.'s ("Reckitt") arguments remain unaddressed. Plaintiffs contend that reconsideration is not appropriate, but even they cannot cite anywhere that the Court addressed superseding causation, Reckitt Benckiser Group, plc's ("RBG") market power, or the *de minimis* presumption applicable to product disparagement. Instead, plaintiffs note that these issues were properly presented, then argue that the Court must have implicitly resolved them.

Simply put, plaintiffs are mistaken. Of course the issues were properly presented; otherwise a motion for reconsideration would be improper. *See, e.g., 3039 B St. Assocs. v. Lexington Ins. Co.*, 740 F. Supp. 2d 671, 674 (E.D. Pa. 2010). What matters is that they were not actually addressed. Nor could the Court have addressed the new evidence—the FDA's *Sixth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions* ("FDA Report")—that Reckitt submitted in conjunction with its motion.

Reconsideration is therefore appropriate. *Blue Mountain Mushroom Co. v. Monterey Mushroom, Inc.*, 246 F. Supp. 2d 394, 398-99 (E.D. Pa. 2002). This Court should reconsider its December 3rd ruling to address the three issues that Reckitt properly raised, but were not decided. On each issue, moreover, Reckitt should prevail for the reasons explained below.

## I. RECONSIDERATION OF THE PETITIONING CLAIMS IS WARRANTED

Reckitt presented two grounds for reconsidering the Court's refusal to dismiss plaintiffs' citizen-petition claims. First, Reckitt presented previously unavailable evidence that contradicts any allegation "that the FDA violated 21 U.S.C. § 355(q)(1)(A)." (Dkt. No. 99-1 ['Mot.'] at 2, 5-6 (quoting Dkt. No. 97 ['Op.'] at 33).) Second, Reckitt asked the Court to address its superseding causation argument that any hypothetical violation of the statute by the FDA would relieve Reckitt from liability. (*Id.* at 2, 6-8.) Plaintiffs' response fails as to both grounds. (*See* Dkt. No. 114 ['DP Opp'n'] at 3-12; *cf.* Dkt. No. 115 ['EP Opp'n'] at 2 n.4.)

### A. The FDA Report Explains The Absence Of Any Allegations That The FDA Violated 21 U.S.C. § 355(q)(1)(A) In This Case

Plaintiffs do not deny that, to prevail on their citizen-petition claims, they must plead that the FDA violated its governing statute by delaying ANDAs in response to Reckitt's petition. (*See, e.g.*, DP Opp'n at 9 (conceding "the FDA's failure to comply with the statutory mandate").) Nor do plaintiffs deny that the FDA Report states that no such delay took place. Finally, plaintiffs do not—and cannot—dispute that the Court may take judicial notice of the FDA Report, the authenticity of which is unquestioned. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004).

Instead, plaintiffs only dispute *how* the Court may *use* the FDA Report *after* it takes judicial notice. (*See, e.g.*, DP Opp'n at 5-6 ("[N]either the Court nor the parties can conclude from the Report alone that Reckitt's CP did not delay the generics entry into the marketplace.").)

Plaintiffs mischaracterize Reckitt's argument. Reckitt did *not* ask the Court to take notice of "the truth and accuracy of the" FDA Report, nor to find that "the Report's contents had been established." (*Id*. at 4.) Rather, Reckitt asked the Court to reconsider the sufficiency and plausiblity of plaintiffs' allegations of a statutory violation in light of the FDA Report—regardless whether that report is true or false. (Mot. at 1-2 ("In light of this new evidence, this Court should reconsider the adequacy and plausibility of plaintiffs' allegations that the FDA may have delayed generic Suboxone ANDAs because of Reckitt's petition.").)

Courts have long condoned such consideration of the adequacy of pleadings in light of matters of which the Court may take judicial notice. (*See* Mot. at 5 (citing *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001) ("[T]hus a court need not feel constrained to accept as truth . . . pleadings . . . that are contradicted . . . by facts of which the court may take judicial notice.")).) Cases relying on judicially-noticeable documents to dismiss as insufficient or implausible conclusory allegations to the contrary abound. *See Lynch*

*ex rel. Finisar Corp. v. Rawls*, 429 F. App'x 641, 645 (9th Cir. 2011) (affirming dismissal of securities-fraud claim based on contents of judicially-noticeable SEC filing, noting that "[w]hile a court need not accept [the facts in the judicially-noticed filing] as true, under *Iqbal*, it may consider it as an alternative explanation more plausible than Plaintiffs' allegations." (citation omitted)); *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) (similar).[1]

Applying these cases here begins with the complaint, which alleges only that the FDA may violate the statute by delaying an ANDA. (*E.g.*, Dkt. No. 47 at ¶¶ 72-73.) The complaint does not allege any non-conclusory fact to indicate that any such delay occurred in the case of Suboxone tablets. The Court nonetheless found those allegations sufficient, at least in the absence of any indication to the contrary. (Op. at 33.) But now the record has changed. The Court may take judicial notice that the FDA expressly denies that any such delay occurred here. That evidence is neither binding on the Court nor dispositive of the issue, but it does render implausible any inference that an *actual* delay occurred in this case based solely on the fact that such a delay may occur in any given case.

In sum, Reckitt's motion was entirely consistent with the authorities on which plaintiffs rely. Reckitt does not ask the Court to find, as an established fact, that the Report is accurate—that FDA did not violate 21 U.S.C. § 355(q)(1)(A) by delaying generic ANDAs in response to Reckitt's petition. Instead, Reckitt asks this Court to reconsider, in light of the Report, whether plaintiffs have adequately or plausibly alleged that the FDA did commit such a violation *in this instance*. In light of the FDA Report, they have not and cannot.

[1] *See also, e.g.*, *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (taking judicial notice of Patent and Trademark Office file to dismiss conclusory allegations of assignment of patent rights); *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1095 (2d Cir. 1995) (taking judicial notice of guilty plea of ponzi-scheme participants in rejecting conclusory allegation that a separate entity controlled participants); *Caldwell v. Folino*, No. 08-122, 2009 BL 140848, at *3-4 & n.6 (W.D. Pa. June 30, 2009) (taking judicial notice of prison grievance process to dismiss allegation that defendant played a role in that process, stating that "a court need not accept as true allegations that contradict matters properly subject to judicial notice" (quotation marks, alteration, and citation omitted).

**B. Any Violation Of 21 U.S.C § 355(q)(1)(A) Constitutes A Superseding Cause**

Even if the Court were to find plaintiffs' allegations adequate despite the FDA Report, dismissal would still be appropriate. For then plaintiffs would have pled themselves out of court. Any statutory violation by the FDA would constitute a superseding cause. (Mot. at 6-8.)

Plaintiffs respond with two red herrings. First, they contend that, as an affirmative defense, superseding causation cannot be resolved on a motion to dismiss. (DP Opp'n at 8-9 & nn.27-28.) But that is contrary to Third Circuit law. "The District Court properly recognized, however, that the court may conclude as a matter of law that defendants' actions were not the proximate cause of the plaintiff's injury." *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 318 (3d Cir. 1999). The general rule is that "a complaint may be subject to dismissal under Rule 12(b)(6) when an affirmative defense . . . appears on its face." *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 & n.9 (3d Cir. 1994) (citing, *inter alia*, 5A Charles Alan Wright *et al.*, *Federal Practice and Procedure* § 1357); *Image Masters, Inc. v. Chase Home Finance*, 489 B.R. 375, 391 (E.D. Pa. 2013) (Goldberg, J.). Here, assuming *arguendo* that the Court finds that plaintiffs have adequately alleged that the FDA violated 21 U.S.C. § 355(q)(1)(A), Reckitt's superseding causation argument ***based upon that violation*** necessarily appears on the face of the complaint.

Next, plaintiffs argue that "agency incapacity, inaction or lateness does not categorically provide Reckitt with antitrust immunity." (DP Opp'n at 9.) Notably, none of the cases cited by plaintiffs even discuss causation principles, much less superseding causation.[2] More fundamentally, Reckitt is not relying on the FDA's *inaction*. Instead, Reckitt is relying on the

[2] Both *Altria Group v. Good* and *Phonetele, Inc. v. AT&T Co.* involved implied preemption arguments. *See Altria*, 555 U.S. 70, 90 (2004) ("[T]he FTC's inaction with regard to 'light' descriptors [does not] even arguably justif[y] the pre-emption of state deceptive practices rules"); *Phonetele*, 664 F.2d 716, 727 n.32 (9th Cir. 1981) (rejecting implied preemption or immunity due to lack of "plain repugnancy between the regulatory scheme and the antitrust laws"). *Clomon v. Jackson*, 988 F.2d 1314 (2d Cir. 1993), rejected a good-faith defense to statutory damages because the defendant, "as an attorney responsible for ensuring compliance with the laws enforced by the the FTC, . . . cannot contend that he believed the FTC's silence indicated approval of these letters." *Id.* at 1322.

FDA's *action*—namely, the FDA's violation of its statutory obligation not to delay generic ANDAs. That affirmative conduct—like the conduct of the state bar in requiring ABA accreditation in *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 937 F. Supp. 435, 439 (E.D. Pa. 1996), *aff'd*, 107 F.3d 1026, 1035-41 (3d Cir. 1998), and the conduct of the FDA in approving an allegedly false ANDA in *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 116 (E.D.N.Y. 1993)—is what constitutes a superseding cause here, not any FDA inaction.

Plaintiffs do not even try to confront, much less distinguish, *Massachusetts School of Law* or *Barr Labs*. In contrast, plaintiffs do attempt—unsuccessfully—to distinguish two of the Reckitt's other cases. Plaintiffs argue that *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163 (E.D. Pa. 1996), and *Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673 (D. Del. 1998), are not instructive because they focused on the "remote[ness]" of the injury. (DP Opp'n at 11 & n.38.) But that is precisely Reckitt's argument: Plaintiffs' injury here—overpayment for Suboxone—is too remote from Reckitt's submission of an allegedly fraudulent citizen's petition.

*Dow* makes the point. Here, as in *Dow*, plaintiffs' injury stems from purported fraud on a government agency (the allegedly sham petition here, a patent application in *Dow*). *See* 30 F. Supp. 2d at 695. But, as in *Dow*, plaintiffs' losses actually "result from the intervening acts" of that agency. *Id.* Here, the statute commands the FDA to prevent delay without exception—whether the petition is a "sham" or not. Thus, "it is only th[e] intervening decision" of the FDA to delay generic ANDAs "that connect[s]" Reckitt's "fraudulent misrepresentations to the losses suffered by" plaintiffs. *Id.* Indeed, the FDA's intervening violation of its statutory obligations here is even more of a superseding cause than the PTO's decision to issue patents in *Dow* because, unlike the PTO, the FDA did not have any discretion to act contrary to law.

In sum, plaintiffs concede that no injury can be tied to Reckitt's Petition unless it delayed

an ANDA, and that any such delay constitutes a violation of the statute by the FDA. That is all that is needed to establish that the FDA's violation is the superseding cause of the alleged injury. This Court should grant Reckitt's motion for reconsideration and dismiss the petition claims.

## II. THE END-PAYOR PLAINTIFFS CONCEDE THAT RECKITT BENCKISER GROUP, plc LACKS INDEPENDENT MARKET POWER

The Court should also reconsider whether the End-Payor Plaintiffs have adequately alleged § 2 claims against RBG. Plaintiffs concede that they have not alleged "that RBG itself had market power," and that they instead seek to attribute "Reckitt's market power . . . to its parent, RBG." (EP Opp'n at 8-9.) This theory hinges on the assumption that plaintiffs alleged sufficient 'control, direction, or encouragement' on behalf of RBG for it to "be held directly liable **as a single enterprise with**" Reckitt. (*Id.* at 9 (original emphasis).)

Plaintiffs' assumption, based only on the allegation that RBG's "directors approved and directed [Reckitt's] anticompetitive scheme," would turn settled corporate law on its head. (Dkt. No. 48 at ¶ 83.) "It is a general principle of corporate law . . . that a parent corporation . . . is not liable for the acts of its subsidiaries. Thus it is horn-book law that the exercise of the 'control' which stock ownership gives . . . will not create liability beyond the assets of the subsidiary." *United States v. Bestfoods*, 524 U.S. 51, 61-62 (1998) (citations omitted). This principle applies to antitrust claims, just as to other claims.[3] In short, the degree of control necessary to attribute Reckitt's market share to RBG is "complete domination, not only of finances but of policy and business practice in respect to the transaction attacked so that the corporate entity as to this transaction had at the time no separate mind, will or existence of its own." *Craig v. Lake*

[3] *See, e.g., Spanish Broad. Sys. of Fla. v. Clear Channel Commc'ns, Inc.*, 376 F.3d 1065, 1075 (11th Cir. 2004) (affirming dismissal of antitrust claims against parent because "the complaint contains no allegations with respect to control over *day-to-day operations* or general corporate policies" (emphasis added)); *Carribbean Broad. Sys., Ltd. v. Cable & Wireless plc*, 148 F.3d 1080, 1088 (D.C. Cir. 1998) (similar); *cf. In re Ins. Brokerage Antitrust Litig.*, 616 F.3d 300, 341 n.44 (3d Cir. 2010).

*Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988) (citing 1 W. Fletcher, *Cyclopedia of the Law of Private Corporations* § 43.10, at 490). Nothing of the sort is alleged here.

Plaintiffs' cases are not to the contrary. Indeed, *In re Penn. Title Ins. Antitrust Litig.*, 648 F. Supp. 2d 663 (E.D. Pa. 2009), demonstrates plaintiffs' error. Rejecting an argument identical to plaintiffs' here, Judge Yohn held: "Viewing plaintiffs' allegations of 'approval and assent' and 'ownership and control; in a light most favorable to plaintiffs, . . . these allegations amount to nothing more than conduct *typical of any parent or subsidiary*." *Id.* at 689 (emphasis added). Likewise, plaintiffs' Colorado case relied exclusively on a prior decision that found parent liability only because the parent "*sufficiently* control[led]" the subsidiary, such that "the subsidiary *dare not defy* its sole shareholder's policies." *Nobody in Particular Presents v. Clear Channel Commc'ns, Inc.*, 311 F. Supp. 2d 1048, 1069-72 (D. Colo. 2004) (emphases added); *see also Reading Int'l Inc. v. Oaktree Cap. Mgmt. LLC*, 317 F. Supp. 2d 301, 325 (S.D.N.Y. 2003) (liability permitted where parent was "decision making entity" and "calling the shots … daily").

In sum, plaintiffs have not alleged facts to justify an inference of the pervasive domination necessary to attribute Reckitt's market power to RBG. "[T]he unadorned invocation of dominion and control simply is not enough." *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 419 (S.D.N.Y. 2011) (citation omitted); *see also, e.g.*, *Haley Paint Co. v. E.I. DuPond De Nemours & Co.*, 775 F. Supp. 2d 790, 799 (D. Md. 2011). For that reason, this Court should grant reconsideration and dismiss the remaining end-payors' claims against RBG.

## III. THE *DE MINIMIS* PRESUMPTION APPLIES TO THE PRODUCT HOP CLAIM

Finally, both the Direct Purchasers and the End Payors attack Reckitt's third ground for reconsideration, the "strong presumption that statements by competitors have a '*de minimis*' effect on competition." (Mot. at 3-4, 11-15.) The Direct Purchasers present only a procedural argument—that this presumption was not overlooked—and do not incorporate the End Payor's

substantive response. (DP Opp'n at 12-16.) This procedural gambit is doomed by the Direct Purchasers' concession "[t]hat the court 'did not mention' the purported presumption." (*Id.* at 16.) In brief, reconsideration is appropriate where "there were . . . legal issues properly presented but overlooked by the court." *Blue Mountain*, 246 F. Supp. 2d at 388.

In contrast, the End Payors respond on the merits, raising multiple arguments. Initially, they contend that the *de minimis* presumption does not apply here at all both because "plaintiffs do not assert a stand-alone 'product disparagement' or 'misrepresentation' claim" and because "Reckitt did not disparage the product of a rival, but *its own product*." (EP Opp'n at 4-5.)

But Plaintiffs do, in fact, allege stand-alone 'product disparagement' claims. Specifically, this Court dismissed plaintiffs' allegations concerning the shared REMS process. (Op. at 24-29.) Plaintiffs are left only with their petitioning claim, *based upon "false safety concerns*," and their product-hop claim. (Op. at 7 (emphasis added).) Moreover, as to the product-hop claim, this Court held "that simply introducing a new product on the market . . . does not, by itself, constitute exclusionary conduct," but permitted the claim to proceed because "the wrongful conduct included *raising false safety concerns and disparaging*" tablets. (*Id.* at 18 (emphasis added).) Thus, all of plaintiffs' remaining claims are based on Reckitt's disparagement.[4]

Likewise, the argument that the *de minimis* presumption cannot apply to a monopolist's disparagement of its own product ignores that any puffery of a new product necessarily disparages the old one. Thus, in the seminal product-hopping case that originally adopted the *de minimis* presumption, the Second Circuit found that Kodak's marketing efforts—which praised the fine grain of its new film and disparaged the graininess of older film—did not constitute

[4] Accordingly, the End Payor's attempt to distinguish *Tate v Pac. Gas & Elec. Co.*, 230 F. Supp. 2d 1072 (N.D. Cal. 2002), is without merit. That the *de minimis* presumption may be fact-dependent does not relieve plaintiffs of their obligation to plead facts that, if proven through discovery, would suffice to defeat it. The antitrust conspiracy claim dismissed in *Twombly* itself was no less fact dependent than the *de minimis* presumption here, but the Supreme Court still held it was subject to dismissal on a Rule 12(b)(6) motion.

exclusionary conduct. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 278 & n.17, 288 & n.41 (2d Cir. 1979). Likewise, in *Walgreen Co. v. Astrazeneca Pharms. L.P.*, the court relied on *Berkey* to conclude that the *de minimis* assumption required dismissal of a complaint alleging "distortion in [the defendant's] efforts to persuade doctors" to prescribe its new product rather the old one. 534 F. Supp. 2d 146, 152 (D.D.C. 2008).

Having failed to show that the *de minimis* presumption does not apply at all, the End Payors next argue it cannot apply in the Third Circuit. (EP Opp'n at 4 n.15.) But they ignore the fact that the Middle District of Pennsylvania explicitly adopted the presumption in a decision that the Third Circuit affirmed. *Santana Products v. Bobrick Washroom Equip., Inc.*, 249 F. Supp. 2d 463, 517 n.47 (M.D. Pa. 2003), *aff'd in relevant part*, 401 F.3d 123, 132 (3d Cir. 2005).

Finally, the End Payors' attempt to take on each of the elements of the presumption. To show "clear falsity," they rely on both their ipse dixit allegation that "unit-dose packaging brought no added measure of safety" and on Reckitt's six-month delay in withdrawing tablets. (EP Opp'n at 5 & n.21 (citing Dkt. No. 48 at ¶ 25).) But the End Payors simply ignore the evidence that generic manufacturers *agree* with Reckitt about the benefits of unit-dose packaging, (Mot. at 13 & Exh. B), and that the six-month delay was required by law. 21 U.S.C. § 356c.

The End Payors' argument regarding "knowledge of the subject matter" is logically incoherent. They contend that "the 'buyers' of the product consist of the various consumer plaintiffs." (EP Opp'n at 6.) But in the very next paragraph, End Payors concede that "doctors make the product selection." (*Id.* at 7.) Thus, doctors—the individuals who select the product—are the relevant focus of the *de minimis* presumption. *See, e.g., Walgreen*, 534 F. Supp. 2d at 152 (holding that plaintiffs could not overcome *de minimis* presumption because "Nexium sales necessarily depended on prescriptions written by medical professionals, that is, persons

knowledgeable of the subject matter"). End Payors' attack on Reckitt's marketing efforts as irrational is contrary to fundamental antitrust law. "[V]igorous advertising is a sign of competition, not a lack thereof." *Apple Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1199 (N.D. Cal. 2008).

Finally, the *de minimis* presumption cannot be overcome in the absence of any allegation that generics lack the ability to "neutralize" Reckitt's alleged disparagement. The Court asked a simple question at oral argument: "[W]hat prevents Actavis or any other generic from trying to convince the doctor that they should . . . prescribe the generic?" (Dkt. No. 96 at 50.) The End Payors offer the same answer now as they did then: "[I]t is not economically feasible for generic manufacturers to use sales force detailers to visit doctors." (EP Opp'n at 8.) Under this view, generic sellers are protected by the *antitrust* laws from having to compete as hard as Reckitt. But no principle of antitrust law protects the generics' desire to free-ride on Reckitt's efforts or mandates that Reckitt "subsidiz[e] its competitors' selling costs." *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986); *see also id.* at 377-78 (competitors have "no right under antitrust law to take a free ride on its competitor's sales force.").

In sum, neither the Direct Purchasers nor the End Payors have alleged any facts that, if proved, could rebut the *de minimis* presumption. This Court should grant Reckitt's motion for reconsideration, address this issue, and dismiss the product-hop claims.

## CONCLUSION

Reckitt respectfully requests that the Court grant its motion for reconsideration.

Dated: January 28, 2014

**Respectfully submitted,**

/s/ Kevin D. McDonald

Kevin D. McDonald
Mark R. Lentz
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700
E-mail: kdmcdonald@jonesday.com
E-mail: mrlentz@jonesday.com

Kimberly A. Brown
JONES DAY
500 Grant Street, Suite 4500
Pittsburgh, PA 15219
Telephone: (412) 391-3939
Facsimile: (412) 394-7959
E-mail: kabrown@jonesday.com

Thomas Demitrack
Brett Bell
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114-1190
Telephone: (216) 586-3939
Facsimile: (216) 579-0212
E-mail: tdemitrack@jonesday.com
E-mail: bbell@jonesday.com

*Counsel for Defendants Reckitt Benckiser Inc.; Reckitt Benckiser LLC; Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) Ltd.; and Reckitt Benckiser Group plc.*